



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,781	01/11/2001	Elliott Farber	14358-308	1721

24633 7590 07/01/2003

HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 07/01/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,781

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-16,18-47 and 49-81 is/are pending in the application.
- 4a) Of the above claim(s) 6-15,23-46 and 54-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-16,18-22,47,49 and 50 is/are rejected.
- 7) ☒ Claim(s) 51-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Amendment filed on April 15, 2003 has been entered. Claims 1-5, 16-22 and 47-53 are drawn to the elected species and the search is accordingly directed to these claims as set forth in Paper No. 11.

1. Claims 6-15, 23-46, 54-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Any rejection that is not addressed in this Office Action is considered obviated. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 1, 3, 16, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation).

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Kuroda's compositions are ineffective below pH of 4.0 and have a reduction in allantoin concentration at pH value between 6-7. Applicant further argues that Kuroda does not teach anionic or nonionic emulsifier nor an emulsifier system comprising an acidic anionic polymer and an anionic emulsifier. *Amendment at p.8.*

In response Examiner states that Kuroda has explicitly taught the use of anionic or non-ionic surfactant. *JP '013 at p. 3-4.* Further, Kuroda teaches allantoin compositions comprising Carbopol 934 (carboxyvinyl polymer which is the same

Art Unit: 1617

polymer as carboxypolymethylene) is an acidic anionic polymer. Thus, Kuroda provides for anionic polymers. Finally, the pH ranges of Kuroda overlaps with those instantly claimed. Accordingly, JP '013 meets all the limitations of the instant claims and is thus an anticipatory reference.

3. Claims 1, 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyder US Patent 4,806,262.

4. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that Snyder does not teach the stability limitation of the instant claims at pH of from about 4.5-8.5. *Amendment at p. 9*. In response, Examiner states that when prior art teaches a range within, overlapping, or touching the claimed ranges, the prior art is anticipatory if it provides for the claimed ranges with sufficient specificity. *MPEP 2131.03*. In the instant case, Snyder teaches emulsions comprising allantoin, Carbopol, a nonionic surfactant (ethoxylated non-ionic surfactant, see claim 1 and example 1). Snyder then explicitly states that the composition should have a pH of about 4.5 to about 8.5, which greatly overlaps with the instant ranges of 3 to about 6. Accordingly, there is sufficient specificity within the teaching of Snyder that the final compositions of Snyder contain allantoin, a non-ionic surfactant and have a pH range of between 4.5-8.5. Applicant has not provided any evidence showing the contrary. Thus, the claims stand rejected.

5. Claims 1, 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlen US Patent 4,707,354.

Art Unit: 1617

6. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that Garlen does not suggest stability or effectiveness across any pH range or at any pH values above or below 5. *Amendment at p. 11*. Applicant further adds that Garlen does not teach emulsifiers, which are substantially hydrophilic, and is soluble in water. *Id.*

In response Examiner first states that the scope of the pending claims is inclusive to all components taught by Garlen, because the transitional phrase "comprising" does not exclude any components of Garlen. Second, under the principles of inherency, a prior art that does not expressly disclose claim limitations anticipates the claims, if it necessarily functions in accordance with, or includes, those limitations. *Atlas Powder Co. v. IRECO Inc.* 190 F.3d 1342, 1349 (Fed. Cir. 1999). Inherency is not necessarily coterminous with knowledge of those of ordinary skill in art, since artisans of ordinary skill may not recognize inherent characteristics or functioning of prior art, but discovery of previously unappreciated property of prior art composition or of scientific explanation for prior art's functioning, does not render old compositions patentably new to discoverer. *Id.* Accordingly, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

In the instant case, the pending claims require emulsions comprising similar elemental components as those claimed here. Galen's composition contains allantoin, a non-ionic emulsifier in a pH ranges between 3-6. Garlen's compositions comprise allantoin, a non-ionic emulsifier such as PEG-100 stearate or glycerly stearate,

Art Unit: 1617

emollients such as cetyl alcohol, vegetable oil, and acceptable topical carriers at a pH of approximately 5 (see col 3-5). Since, Garlen's composition comprise all elemental components of the instant claims, it is also capable of possessing the same functional characteristics as instant compositions. Accordingly, Garlen's allantoin is inherently stable at pH of about 5, which falls within the range of the instantly claimed compositions. Thus, Garlen anticipates the instant claims.

Claim Rejections - 35 USC § 103

7. Claims 1, 3-5, 16, 18--22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '013 in view of Grollier et al US Patent 4,767,618 and Garlen US Patent 4,707,354.

8. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the rejection is based on the combined teachings of the references as of record. Further, as explained above, alleged shortcomings of individual references were rebutted. Therefore, the combined teachings of the references render the claims obvious for the reasons of record.

10. Moreover, each and every element of the pending claims are taught in the combined teachings of the references. Accordingly, since no unexpected results were

Art Unit: 1617

presented, the rejection of record is proper because all elements of the claims are met and one of ordinary skill in the art would have had a reasonable expectation of success in formulating a stable topical emulsion for the reasons of record.

11. Claims 1, 3-4, 47, 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garlen US Patent 4,707, 354 in view of Goode et al US Patent 4,822,601 and France US Patent 4,767,618.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413; *In re Merck & Co.*, 800 F.2d 1091. For the same reasons as argued above in para 9-10, the combined teachings of the references render the claims obvious for the reasons of record.

Claim Objections

12. Claims 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1617

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

June 20, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200